1171-01EA

Hospira

MATERIAL SAFETY DATA SHEET

Product Name: Diltiazem Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone Hospira, Inc.	CHEMTREC: 800 424-9300 224 212-2055
Product Name	Diltiazem Hydrochloride Injection
Synonyms	None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	Diltiazem Hydrochloride Injection
Chemical Formula	$C_{22}H_{27}ClN_2O_4S$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Diltiazem Hydrochloride	0.5	33286-22-5	N/A
Sorbitol	7.1	50-70-4	LZ4290000
Water	92	7732-18-5	ZC0110000

Note: Diltiazem Hydrochloride is also available in the ADD-Vantage Vial and will appear as an off-white crystalline powder.

3. HAZARD INFORMATION

Emergency Overview	In clinical use, this material is used to treat cardiac ailments and hypertensive crises. The active ingredient is toxic by ingestion. Possible target organs include the heart, cardiovascular system, liver, kidneys and fetus.
Occupational Exposure Potential	Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	No signs or symptoms from occupational exposure are known. Clinical data suggest the following: edema, headaches, nausea, dizziness, rash, excessive urination, cardiac changes, constipation, dyspepsia, decreased blood pressure, slow heart rate, sleep, muscle weakness, insomnia.
Medical Conditions Aggravated by Exposure	Hypersensitivity to the material. Data suggest any preexisting ailments in the following organs: kidney, liver, heart. Concurrent use of medications.

4. FIRST AID MEASURES

Eye Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability:	Non-flammable.
Fire & Explosion Hazard:	None
Extinguishing Media:	Use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling	Keep under refrigeration. Do not freeze.
Storage	No special storage required for hazard control. For product protection store under refrigeration at temperature of 2-8 °C (36-46 °F). May be stored at room temperature for up to one month. Destroy after one month at room temperature.
Special Precautions	Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Diltiazem Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 20 mcg/m3 STEL:Not Established
Sorbitol	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State:	Clear, colorless solution **Note:** Diltiazem Hydrochloride is also available in the ADD-Vantage Vial and will appear as an off-white crystalline powder.
Odor	None
Boiling Point	Approximately that of water (100 °C, 212 °F).
Freezing Point	Approximately that of water (0 °C, 32 °F).
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C).
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	Approximately that of water (1.0).
Solubility	Water soluble
pH	3.7 – 4.1

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	None
Hazardous Decomposition Products	Toxic fumes of HCl and oxides of nitrogen
Hazardous Polymerization	Not Determined.

11. TOXICOLOGICAL INFORMATION:

Toxicity

Ingredient(s)	Percent	Test Type	Value	Units	Species
Diltiazem Hydrochloride	100	LD50	470-810	mg/kg	Rats, Mice
Sorbitol	100	LD50	15900-17800	mg/kg	Rats, Mice

LD50 is the dosage producing 50% mortality.
Product contains approximately 0.5% Diltiazem Hydrochloride.

Mutagenicity	Negative in the Ames Test. Negative in the chromosomal aberration assay. Negative in the micronucleus test.
Target Organ Effects	In clinical use target organ effects include the heart. Diltiazem is a calcium channel blocker used to treat angina, cardiac ailments and hypertensive crises. Diltiazem alters the coduction in the heart. In animal studies, dosages above 2.5 mg/kg/day produced embryolethality, skeletal abnormalities, and fetotoxicity while dosages of 5 mg/kg/day or more altered kidney and/or liver function.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	Disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT	Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Not Regulated
CERCLA Status	Not Regulated
SARA Status	Not Regulated
RCRA Status	Not Regulated
PROP 65 (Calif.)	Diltiazem Hydrochloride is identified in the state of California to cause reproductive toxicity.

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator	Global Occupational Toxicology
Date Prepared	September 15, 2005
Date Revised	October 21, 2008

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